IN THE MATTER OF

ALGUNAS, INC. d/b/a WOODLAND HILLS PHARMACY

PERMIT NO. P06088

* BEFORE THE

* STATE BOARD

* OF PHARMACY

Respondent-Pharmacy

* Case No.: PI-17-251

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FINAL CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board"), and subject to Md Code Ann., Health Occ. §§ 12-101, et seq., (2014 Repl. Vol. and 2018 Supp.) (the "Act"), on April 23, 2019, the Board issued Charges against the pharmacy permit of ALGUNAS, INC. d/b/a WOODLAND HILLS PHARMACY, PERMIT NO. P06088 (the "Respondent-Pharmacy"). On August 14, 2019, a telephonic Case Resolution Conference was held with the Respondent-Pharmacy's Owner and primary dispensing Pharmacist, Steven Levin, R. Ph., who was not represented by Counsel, (and knowingly and voluntarily waived his right to same), members of the Board, along with Board Counsel, and the Administrative Prosecutor, in order to determine whether the matter could be resolved. As a result, the following settlement was reached.

The pertinent provisions of the Act provide the following:

Specifically, the Board charged the Respondent-Pharmacy with violation of the following provisions of § 12-409:

- (a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:
 - (2) Violates any of the standards specified in § 12-403 of this subtitle [;].

§ 12-403 Required standards

...

- (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title [;].
- (f) A nonresident pharmacy shall:
 - (1) Comply with the laws of the state in which it is located [;].

§ 12-313. Denials, reprimands, suspensions, and revocations

- (b) Subject to the hearing provisions of §12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant, reprimand any licensee, place any licensee on probation; or suspend or revoke a license if the applicant or licensee:
 - (1) Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another;
 - (7) Willfully makes or files a false report or record as part of practicing pharmacy;
 - (24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes; [and]
 - (25) Violates any rule or regulation adopted by the Board [.]

The underlying grounds for discipline under Health Occ. § 12-313(b) (25) are as follows:

Md. Code Regs. 10.31.10.01 Patient Safety and Welfare.

B. A pharmacist may not:

¹ With underlying grounds of Health Occ. §§ 12-313(b) (1), (7), and (25).

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;
- (3) Engage in unprofessional conduct.

FINDINGS OF FACT

- 1. At all times relevant to the charges herein, the Respondent-Pharmacy is a pharmacy in Woodland Hills, California. The Pharmacy is registered with the Board as a non-resident pharmacy authorized to operate in the State of Maryland. Its permit was first issued on May 6, 2014. Its expiration date is May 31, 2020.
- 2. At all times relevant hereto, the Respondent-Pharmacy's Owner² is licensed to practice pharmacy in Maryland. The Owner was first issued a Maryland pharmacist license on April 8, 2014. The Owner's license is current through December 31, 2019.
- 3. On or about March 5, 2018, the Owner notified the Board that the California Board of Pharmacy (the "California Board") issued an Order on February 9, 2018, which revoked the Respondent-Pharmacy's California pharmacy license, stayed the revocation, and placed the Respondent-Pharmacy on probation for four years. The Owner's pharmacy license was also revoked, immediately stayed, and placed on probation with certain terms and conditions.
- 4. As a result of the California Board's Order, the Board opened an investigation of the Respondent-Pharmacy.

INVESTIGATION

A. Prior Disciplinary History

5. As a part of its investigation, the Board conducted a search of licensing disciplinary orders from other jurisdictions against the Respondent-Pharmacy and its Owner. The Respondent-Pharmacy's disciplinary history is set forth *infra*.

2015 Alabama Order

- 6. On or about January 27, 2015, the Alabama State Board of Pharmacy (the "Alabama Board") issued a Final Order denying the Owner's initial application for a pharmacist license.
- 7. The 2015 denial from the Alabama Board was based upon the following grounds:
 - A. On January 4, 2012, the California Board disciplined the Owner by assessing a monetary fine of \$4,000, based on the Owner's failing to maintain proper records, policies and procedures.
 - B. On March 6, 2012, the California Board disciplined the Owner by assessing a monetary fine of \$2,500, based on the Owner's allowing a clerk to perform unauthorized duties and failing to follow requirements for compounded products.
 - C. On May 10, 1983, the Owner pled guilty and was found guilty of the Transport/Import/Sale of Marijuana in California.

² The names of individuals and facilities are confidential.

2015 Oregon Order

8. On or about April 22, 2015, the Oregon Board of Pharmacy (the "Oregon Board") entered a Consent Order with the Owner which imposed a fine and required completion of continuing education. The 2015 Consent Order from the Oregon Board arose from the Owner's failure to disclose his 1983 conviction for Transport/Import/Sale of Marijuana in California on his initial application for licensure.

2015 South Carolina Order

- 9. On or about September 18, 2015, the South Carolina State Board of Pharmacy (the "South Carolina Board") issued an Order denying the Respondent-Pharmacy's application for licensure.
- 10. The 2015 Order from the South Carolina Board was based on the following grounds:
 - A. The Respondent-Pharmacy failed to perform salt to base conversions for pain creams not consistent with current pharmacy compounding standards.
 - B. The Respondent-Pharmacy failed to have policies and procedures that are customized to the business.

2016 Louisiana Order

11. On or about March 11, 2016, the Louisiana Board of Pharmacy (the "Louisiana Board") entered a Consent Order with the Owner which reprimanded the Owner and imposed a fine. The 2016 Consent Order from the Louisiana Board arose from the Owner's

failure to disclose his 2015 discipline from the Oregon Board on his 2016 application for license renewal in Louisiana.

2017 Texas Order

12. On or about January 9, 2017, the Texas State Board of Pharmacy (the "Texas Board") issued an Order imposing a fine on the Owner. The 2017 Order from the Texas Board arose from the Owner's failure to report the 2015 Order from the Alabama Board, the 2015 Order from the Oregon Board, and the 2015 Order from the South Carolina Board, on the Respondent-Pharmacy's application for renewal.

2017 Nebraska Order

13. On or about February 7, 2017, the State of Nebraska Department of Health and Human Services issued an Order on Agreed Settlement which imposed a fine on the Owner. The 2017 Nebraska Order arose from the Owner's failure to disclose the 2015 denial from the Alabama Board, the 2015 Order from the Oregon Board, the 2016 Order from the Louisiana Board, and the 1983 Transport/Import/Sale of Marijuana conviction in California, on his 2016 application for reinstatement of his pharmacist license in Nebraska.³

B. 2016 Non-Resident Pharmacy Permit Renewal

14. On or about March 18, 2016, the Board received the Respondent-Pharmacy's application for renewal of its permit.

³ On December 13, 2017, the Maryland Board issued the Owner a Letter of Admonishment based upon his failure to disclose that he had been disciplined by the Nebraska Board. That Nebraska Board Order referenced the aforesaid California marijuana conviction as well as the California disciplinary action arising therefrom and the aforesaid disciplinary actions in Alabama, Oregon and Louisiana. It did not reference the South Carolina disciplinary Order.

15. In the renewal application, the Owner answered "N" (No) to a question which stated:

Do you have a Disciplinary Document that needs to be attached? If so, select Y.

16. The Owner willfully failed to disclose that the South Carolina Board denied the Respondent-Pharmacy's application for licensure in 2015.

C. 2018 California Order

- 17. On or about November 3, 2017, the Owner signed a "Stipulated Settlement and Disciplinary Order" (the "California Order"), with the California Board. The California Order became effective February 9, 2018. The bases of the discipline were as follows, *inter alia:*
 - A. Between January 15, 2014 and May 8, 2015, at least 249 prescriptions of amphotericin⁴ were found to be dispensed that were found to be adulterated and lacking in potency;
 - B. During the California Board's inspection of the Pharmacy on May 11, 2015, it was revealed that the Owner compounded amphotericin using incorrect procedures, including using a hot plate instead of a cold plate, and that the final amphotericin preparation was packaged in a plastic polypropylene container, which resulted in polymer degradation and caused the amphotericin to fail to meet its stated quality and strength;

⁴Amphotericin B is an antifungal medicine used to treat certain kinds of fungal or yeast infections.

- C. Between January 15, 2014 and May 8, 2015, the Owner dispensed at least 249 prescriptions of amphotericin that had not been properly stored and delivered;
- D. The Master Formula for the amphotericin required that the compounded medication be refrigerated and protected from light. However, the compounded medication was not packaged in a light-sensitive container and was shipped without proper refrigeration;
- 18. The California Order revoked the Owner's license, stayed the revocation, and placed him on Probation for four years with conditions, such as: the Owner shall be restricted from the practice of pharmacy compounding until he has satisfactorily completed a California Board-approved remedial compounding course within one year of the effective date and at least six hours of compounding related courses prior to resuming compounding activities; the Owner shall submit to the California Board for prior approval a community service program in which the Owner shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 32 hours per year; the Owner shall not acquire new ownership or serve as manager, administrator, etc., of any corporation licensed by the California Board; and, the Owner shall take a Board-preapproved ethics course. The California Order also revoked the Respondent-Pharmacy's license, but stayed the revocation and placed the license on Probation for four years.

D. Reciprocal Actions Based on 2018 California Order

- 19. Following the 2018 California Order, the following jurisdictions have taken reciprocal actions against the Respondent-Pharmacy's and/or the Owner's pharmacy licenses/permits/registrations:
 - A. On or April 26, 2018, the Nevada State Board issued an Order approving the Owner's license for renewal, but placing it on Probation subject to full compliance of the 2018 California Order;
 - B. On or about May 23, 2018, the Louisiana Board issued an Order suspending the Owner's license for 3 years, 9 months, and 17 days, immediately stayed the suspension, and, placed the license on probation subject to full compliance of the 2018 California Order;
 - C. On or about June 27, 2018, the Virginia Department of Health Professions issued an Order which cited the California Board's Order as the basis to suspend the registration of the Respondent-Pharmacy to conduct business as a non-resident pharmacy in Virginia;
 - D. On or about September 11, 2018, the Oregon Board entered a Consent Order with the Owner which placed the Owner on Probation for the duration of the California Board's Probation, requiring him to comply with the terms of the California Board's probationary conditions.

GROUNDS FOR DISCIPLINE

- 20. The Owner's failure to report the 2015 Order from the South Carolina Board on the Respondent-Pharmacy's 2016 Maryland renewal application, constitutes: fraudulently or deceptively obtaining or attempting to obtain a license in violation of Health Occ. § 12-313(b)(1); willfully making or filing a false report or record as part of practicing pharmacy in violation of Health Occ. § 12-313(b)(7); and violating any rule or regulation adopted by the Board, *i.e.* engaging in unprofessional conduct subject to COMAR 10.31.10.01(B)(3), in violation of Health Occ. § 12-313(b)(25).
- 21. The Respondent-Pharmacy's willful failure to disclose relevant and material information in various licensing applications, which was the subject of discipline in the 2015 Oregon Order, the 2015 South Carolina Order, the 2016 Louisiana Order, the 2017 Texas Order, and the 2017 Nebraska Order, constitutes violation of: Health Occ. § 12-313(b)(1) (Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another); § 12-313(b)(7) (Willfully makes or files a false report or record as part of practicing pharmacy); and § 12-313(b)(25) (Violates any rule or regulation adopted by the Board, *i.e.* COMAR 10.31.10.01(B)(3) (A pharmacist may not engage in unprofessional conduct)).
- 22. The Owner's failure to adhere to standard of care ordinary exercised by a pharmacist, which is the subject of the 2018 California Order, constitutes a violation of: Health Occ. § 12-313(b) (25) (Violates any rule or regulation adopted by the Board, *i.e.*

COMAR 10.31.10.01(B) (1) (A pharmacist may not engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist)).

23. The failure of the Respondent-Pharmacy to comply with the laws of its own State is in violation of §12-403 (f) (1).

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated § 12-409 (a) (2), § 12-403 (9) (f) (1) and §§12-213 (1), (7), (24) and (25) of the Act and COMAR 10.34.10.10 (B). (1) and (3).

<u>ORDER</u>

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this general day of November 2019, by a majority of a quorum of the Board,

ORDERED that the Respondent-Pharmacy's permit be placed on Probation retroactively to run concurrently with the California Board Order.

During the effective period of the Probation:

1. The Owner shall ensure that the Respondent-Pharmacy shall be inspected at least annually by the California Board and that those inspection reports be sent to the Maryland Board. In addition, the Owner shall forward to the Maryland Board the monthly reports of the Consultant required by the California Board Order and the VBP

inspection reports;

- 2. Any flaws in the California inspection reports deemed to be of concern to the public health, welfare and safety will cause the Maryland Board to issue an Order requiring the Respondent-Pharmacy to halt the shipment of products to Maryland residents until that problem is solved to the satisfaction of the Maryland Board;
- 3. Any violation of the California Probation/Order shall be deemed a violation of the Maryland Order.

ORDERED that the Respondent-Pharmacy may petition for termination of Probation after successful completion of the California Board Probation, as demonstrated by an Order terminating same.

ORDERED that the Consent Order is effective as of the date of its signing by the Board; and be it

ORDERED that the Respondent-Pharmacy shall practice in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and be it further

ORDERED that, should the Board receive information that the Respondent-Pharmacy has violated the Act or if the Respondent-Pharmacy violates any conditions of this Order or of Probation, after providing the Respondent-Pharmacy with notice and an opportunity for a hearing, the Board may take further disciplinary action against the Respondent-Pharmacy, including suspension or revocation. The burden of proof for any

action brought against the Respondent-Pharmacy as a result of a breach of the conditions of the Order or of Probation shall be on the Respondent-Pharmacy to demonstrate compliance with the Order or conditions; and be it

ORDERED, that for purposes of public disclosure, as permitted by Md. General Provisions. Code Ann.§§ 4-101, et seq. (Vol. 2014 and 2018 Supp.), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law and Order, and that the Board may also disclose same to any national reporting data bank that it is mandated to report to.

Kevin Morgan, Pharm.D., Presid

State Board of Pharmacy

CONSENT OF STEVEN LEVIN, R. PH., Owner, on behalf of ALGUNAS, INC. d/b/a WOODLAND HILLS PHARMACY, PERMIT NO. P06088

I, Steven Levin, R. Ph. acknowledge that I am not represented by counsel and have

knowingly and voluntarily waived my right to be so represented before entering this Consent

Order. By this Consent and for the purpose of resolving the issues raised by the Board, I

agree and accept to be bound by the foregoing Consent Order and its conditions.

I acknowledge the validity of this Consent Order as if entered into after the

conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to

confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other

substantive and procedural protections provided by the law. I agree to forego my

opportunity to challenge these allegations. I acknowledge the legal authority and jurisdiction

of the Board to initiate these proceedings and to issue and enforce this Consent Order. I

affirm that I am waiving my right to appeal any adverse ruling of the Board that might have

followed after any such hearing.

I sign this Consent Order, voluntarily and without reservation, after having an

opportunity to consult with counsel, and I fully understand and comprehend the language,

meaning and terms of this Consent Order.

Date

Steven Levin, R. Ph.

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STATE OF <u>California</u>: CITY/COUNTY OF <u>Los Angeles</u>:

I HEREBY CERTIFY that on this 31 day of October 2019, before me, Dany A. Rosales, a Notary Public of the foregoing State and (City/County), (Print Name) personally appeared Steven Levin, R. Ph., License No. 22295, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

DANNY A, ROSALES Notary Public - California Los Angeles County Commission # 2206941 My Comm. Expires Jul 24, 2021

Notary Public

My Commission Expires: